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INTERNATIONAL PRELIMINARY REPORT ON PATENTAB
(Chapter II of the Patent Cooperation Treaty)

REC'D 05 NOV 2004

IPEA

PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 03op133p	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/KR2004/000092	International filing date (day/month/year) 19 JANUARY 2004 (19.01.2004)	Priority date (day/month/year) 23 JANUARY 2003 (23.01.2003)	
International Patent Classification (IPC) or national classification and IPC IPC7 A61K 9/16			

Applicant

AMOREPACIFIC CORPORATION et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____ containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I Basis of the report
<input type="checkbox"/>	Box No. II Priority
<input type="checkbox"/>	Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI Certain documents cited
<input type="checkbox"/>	Box No. VII Certain defects in the international application
<input type="checkbox"/>	Box No. VIII Certain observations on the international application

Date of submission of the demand 23 JULY 2004 (23.07.2004)	Date of completion of this report 27 OCTOBER 2004 (27.10.2004)
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Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer Yoon, Kyung Ae Telephone No. 82-42-481-5605
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/000092

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):
 - the international application as originally filed/furnished
 - the description:
pages _____ received by this Authority on _____ as originally filed/furnished
pages* _____ received by this Authority on _____
 - the claims:
pages _____ as originally filed/furnished
pages* _____ received by this Authority on _____ as amended (together with any statement) under Article 19
pages* _____ received by this Authority on _____ received by this Authority on _____
 - the drawings:
pages _____ as originally filed/furnished
pages* _____ received by this Authority on _____ received by this Authority on _____
 - the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. The amendments have resulted in the cancellation of:
 - the description, pages _____
 - the claims, Nos. _____
 - the drawings, sheet _____
 - the sequence listing (specify) : _____
 - any table(s) related to sequence listing (specify) : _____

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages _____
 - the claims, Nos. _____
 - the drawings, _____
 - the sequence listing (specify): _____
 - any table(s) related to sequence listing (specify) : _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/000092

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-13	YES
	Claims	none	NO
Inventive step (IS)	Claims	1-13	YES
	Claims	none	NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims	none	NO

2. Citations and explanations (Rule 70.7)

The present invention relates to sustained-release preparations characterized by being prepared from double granules which are obtained by primary granulation of a drug according to melt granulation using hydrophobic release-delaying additives, and then by secondary granulation of the obtained granules according to wet granulation using hydrophobic wet-granulation material.

The following documents have been considered for the purpose of this report:

- D1 = WO 99/47128 A1 (23. 09. 1999)
- D2 = US 5807583 A (15. 09. 1998)
- D3 = EP 1125586 A1 (22. 08. 2001)
- D4 = US 2002/102302 A1 (01. 08. 2002)
- D5 = US 5451409 A (19. 09. 1995)

D1 discloses a biphasic controlled release delivery system for high solubility pharmaceuticals, which includes an inner solid particulate phase and an outer solid continuous phase.

D2 discloses a process for manufacturing sustained release pellets comprising pelletizing a mixture containing a drug in finely divided form and a water-insoluble wax-like binder.

D3 discloses sustained release particles comprising a drug-containing core substance coated with a mixed coating of a hydrophobic organic compound and water-insoluble polymer, which prevents sticking during compression molding when producing tablets.

D4 describes a stabilized sustained release tramadol tablet containing a hydrophobic material which comprises a wax-like substance.

D5 describes a sustained release matrix and oral dosage form comprising a homogeneous matrix formed from a wet granulation containing a medicament and a polymer blend of HEC and HPC.

(Continued in Supplemental Box)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V.

1. Novelty

None of D1 to D5 relates to sustained-release double granule preparations obtained by primary melt granulation and secondary wet granulation as claimed in the present claims 1 to 13.

Therefore, the subject matter of claims 1-13 can be regarded as novel under PCT Article 33(2).

2. Inventive Step

None of the above-mentioned prior art documents teaches or fairly suggests sustained-release preparations prepared from double granules which are obtained by primary melt granulation and secondary wet granulation using hydrophobic materials such as waxes and fatty acids, nor improved properties of said preparations characterized by minimizing the amount of hydrophobic additives for imparting sustained-releasing property and eliminating an adhesion phenomenon of granules occurring during the tablet preparation. The prior art documents merely refer to sustained-release preparations obtained by either melt or wet granulation. Therefore, the subject matter of claims 1-13 is considered to involve an inventive step under PCT Article 33(3).

3. Industrial Applicability

The subject matter of claims 1-13 is considered to be industrially applicable under PCT Article 33(4).

INTERNATIONAL SEARCH REPORT

International application No. PCT/KR2004/000092
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A. CLASSIFICATION OF SUBJECT MATTER

IPC7 A61K 9/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
KOREAN PATENTS AND APPLICATIONS FOR INVENTIONS SINCE 1975Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
CAPLUS(STN), EMBASE(STN), PASCAL(STN), SCISEARCH(STN), WPI, USPATFULL, JAPIO

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99/47128 A1 (BRISTOL-MYERS SQUIBB COMPANY) 23 SEPTEMBER 1999 see the whole document	1, 4, 5
A	US 5807583 A (PHARMACIA AB) 15 SEPTEMBER 1998 see the whole document	1, 4, 5
A	EP 1125586 A1 (TANABE SEIYAKU CO., LTD.) 22 AUGUST 2001 see the whole document	1
A	US 2002/102302 A1 (OSHLACK, B., HUANG, H.-P., CHASIN, M., GOLDENHEIM, P.) 1 AUGUST 2002 see the whole document	1, 4, 5
A	US 5451409 A (RENCHER, W.F., BABU, S., MUSUNURI, S., DAY, C.H., SCHWING, J.) 19 SEPTEMBER 1995 see the whole document	1

 Further documents are listed in the continuation of Box C. See patent family annex.

- * Special categories of cited documents:
- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

08 JUNE 2004 (08.06.2004)

Date of mailing of the international search report

08 JUNE 2004 (08.06.2004)

Name and mailing address of the ISA/KR



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Authorized officer

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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No. PCT/KR2004/000092
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
W09947128A1	23.09.1999	AU3182899A AU736951B2 BR9908911A CA2320900A1 CN1295467T EA310181 EP1063973A1 JP2002506812T NZ506202A	11.10.1999 09.08.2001 02.10.2001 23.09.1999 16.05.2001 26.12.2002 03.01.2001 05.03.2002 31.10.2003
US5807583A	15.09.1998	AT154756T AU3911193A CA2132451A1 DE69311800D1 DE69311800T2 DK630235T3 EP0630235A1 ES2105240T3 GR3024604T3 JP7505360T SE9200858A W09318753A1	15.07.1997 21.10.1993 30.09.1993 31.07.1997 08.01.1998 02.02.1998 28.12.1994 16.10.1997 31.12.1997 15.06.1995 21.09.1993 30.09.1993
EP1125586A1	22.08.2001	AU6228799A CA2347104A1 CN1331605T W00024423A1	15.05.2000 05.04.2000 16.01.2002 04.05.2000
US20020102302A1	01.08.2002	AU8293498A1 CA2270975AA EP1009387A1 JP2000510487T2 US6306438A W09901111A1	25.01.1999 14.01.1999 21.06.2000 15.08.2000 23.10.2001 14.01.1999
US5451409A	19.09.1995	NONE	